

AMENDMENTS TO THE SPECIFICATION:

Delete Abstract

Replace with:

A method for controlling breast milk leakage in female humans consisting of placing a reusable, washable, thin, flexible, breathable, liquid impervious shield having an exterior frame laminated to an inner membrane against a nipple of a lactating human female; and depressing the nipple, wherein the inner membrane of the shield contacts the nipple.

Page 1, ll. 4-6:

“The present invention relates to an apparatus for controlling leakage of lactating fluid in human females. Specifically, this invention is a thin, multi-layered silicone compound based ~~membrane~~ shield that conforms to the shape of the breast.”

Page 2, ll. 4-13:

“It is well known that a slight direct pressure to the nipple can control and limit leakage. Such a device incorporating this knowledge is disclosed in U.S. ~~patent~~ Patent No. 5,394,899 issued to Morrissey et al. However this type of device is also bulky, presenting an unnatural shape for the breast and uses an absorptive and opaque component. Therefore, there exists a need for a device that can severely limit or eliminate BML and prevent transmission of lactating fluid through undergarments to exterior clothing that is reusable, sanitary, washable, and further does not add bulk to the breast profile, and does not change the shape of the breast. There further exists a need for a device that can control spontaneous BML that can be worn under light and semi-sheer garments with little or no noticeability.”

“Testing of the present invention has indicated that leakage is significantly reduced if not eliminated altogether, and any leakage that does not occur is contained. In one embodiment of the present invention, the construction of the shield allows it to be used without a ~~brasserie~~ brassiere. The shield is used by first placing the shield against the nipple and depressing the nipple; then pressing the shield against the surrounding skin. The inherent tackiness of silicone rubber compounds of low durometer keeps the shield in contact with the skin without the use of adhesives. This gives nursing women freedom from having to wear a ~~brasserie~~ brassiere twenty-four hours a day. The shield also provides insulative properties, keeping the covered area warm; a distinct advantage in comfort over an absorptive nursing pad.

“Two embodiments of the invention are presented herein: a design comprising an outer frame laminated to an inner membrane wherein the inner membrane is sufficiently low in durometer to allow adherence to the skin; the outer frame providing support and shape for the shield, and a design comprising a single membrane of a relatively higher durometer that is held in place by a ~~brasserie~~ brassiere or other article of clothing.”

Page 3, l. 26 - page 4, l. 2:

“The present invention is also directed towards a method of controlling BML that utilizes the shield with a ~~brasserie~~ brassiere. The method includes the steps of placing the shield into the cup of a ~~brasserie~~ brassiere, securing the shield in place using an appropriate adhesive, and placing the ~~brasserie~~ brassiere on the wearer. The device and method of the present invention provide a convenient, economical, sanitary and attractive way to prevent leakage of lactating fluid on to the exterior clothing of the wearer. It is anticipated that the device of the present invention can be incorporated into a manufactured brassiere, by providing the instant invention with a fabric incorporated into or laminated onto the outer frame.”

Page 4, ll. 6-15:

“Accordingly, it is a principal object of the present invention to provide a device that will prevent spontaneous leakage of lactating fluid that does not require the use of an absorbent material. it is a further object of the present invention to provide a device for preventing spontaneous BML that is economical, washable, reusable and sanitary. It is a still further object of the present invention to provide a device that prevents the leakage of lactating fluid to the outer garments of the wearer that conforms to the shape of the breasts of the wearer and that is unnoticeable underneath clothing. It is a still further object of the present invention to provide a device that prevents the leakage of lactating fluid that will adhere to the skin of the wearer without the use of adhesives and that may be utilized with or without supporting outer clothing such as a ~~brasserie~~ brassiere.”

Page 4, ll. 24-25:

“Figure 3 is a view of the shield according to the present invention showing the ~~method for securing~~ the shield secured into a ~~brasserie~~ brassiere.”

Page 4, l. 29:

“Figure 6 is a view of the laminated cloth as an integrated part of a nursing bra shown on a wearer.”

Page 5, ll. 18-27:

“In a preferred embodiment, the shield is constructed of two layers, an outer layer of a higher durometer silicone compound and an inner layer of a lower durometer silicone compound. Other embodiments anticipate the use of a single layer membrane. Testing has shown that ~~Silicone~~ silicone rubbers also exhibit a resistance to lateral stresses and tearing that increase with thickness. The thicker the shield, the more resistant to tearing it is. The minimal thickness of the shield 10 is such that it will not tear when in use. Testing has shown that the shield 10, is functional at thickness less than 100 mils. However, when the shield 10 is

manufactured at small thicknesses, it becomes difficult to handle and tends to fold over and stick to itself. Testing has shown that a thickness range of 20 to 90 mills works well for a consumer product.”

Page 6, ll. 11-15:

“In some embodiments, the shield 10 has no inherent color other than being slightly translucent. Other embodiments of the invention anticipate the use of color additives to the shield 10, ~~as 10, as~~ as 10, as are well known in the art. Such color additives may be present to more closely match the skin tone of the wearer or to provide a decorative effect.”

Page 6, l. 20-31:

“Referring now to Fig. 2, an exterior frame 11 and an interior coating 12 of the shield 10 can be seen. The exterior frame 11 comprises a silicone rubber compound of a comparatively high durometer ~~vise~~ versus the interior coating 12. In a preferred embodiment, the exterior frame 11 comprises injection molding grade silicone rubber compounds with a durometer between 0 and 100 using the Shore A scale. Testing has indicated that the exterior frame 11 is sufficiently stiff at 100 durometer Shore A, although in cases where more stiffness is desired, the exterior frame 11 may exceed 100 durometer ~~shore~~ Shore A. The exterior frame 11 will generally be between 10 mil and 70 mils thick, although for specific applications where greater stability or stiffness is required, the exterior frame may be thicker than 70 mils. Similarly, designs where maximum flexibility and deformability is desired, the exterior frame may be thinner than 10 mils.”

Page 7, ll. 16-20:

“Referring now to Fig. 3, the shield 10 is shown as being secured by a user into a ~~brasserie~~ brassiere 20. In a preferred embodiment, the shield 10 is supplied in a kit to the end-user. The kit will contain an appropriate adhesive 30 as is well known in the art, allowing shield 10 to be secured within the ~~brasserie~~ brassiere

20. This allows the user to “custom fit” the shield 10, ensuring maximum effectiveness.”

Page 7, ll. 24-25:

“Referring now to Fig. 6, manufactured nursing bra 50 is shown as it would be used by a wearer.”